# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

| | | |
|---|---|---|
| Applicant's or agent's file reference<br>665024 | **FOR FURTHER ACTION** | See item 4 below |
| International application No.<br>PCT/JP2005/000786 | International filing date *(day/month/year)*<br>21 January 2005 (21.01.2005) | Priority date *(day/month/year)*<br>23 January 2004 (23.01.2004) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 | | |
| Applicant<br>GREEN PEPTIDE CO., LTD. | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the report |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☐ | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

| | |
|---|---|
| | Date of issuance of this report<br>22 August 2006 (22.08.2006) |
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br>Facsimile No. +41 22 338 82 70 | Authorized officer<br>Masashi Honda<br>e-mail: pt08@wipo.int |

Form PCT/IB/373 (January 2004)

# PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Applicant's or agent's file reference<br>665024 | Date of mailing<br>*(day/month/year)*<br>**FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/JP2005/000786 | 21.01.2005 | 23.01.2004 |

International Patent Classification (IPC) or both national classification and IPC

Applicant
GREEN PEPTIDE CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA/JP | Authorized officer |
|---|---|
| Facsimile No. | Telephone No. |

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2005/000786

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000786

**Box No. V** **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-9 | YES |
| | Claims | 10 | NO |
| Inventive step (IS) | Claims | 2 | YES |
| | Claims | 1, 3-10 | NO |
| Industrial applicability (IA) | Claims | 1-10 | YES |
| | Claims | | NO |

2. Citations and explanations:

Document 1: Okugawa T. et al., A novel human HER2-derived peptide homologous to the mouse K(d)-restricted tumor rejection antigen can induce HLA-A24-restricted cytotoxic T lymphocytes in overian cancer patients and health individuals, Fur. J. Immunol., 2000, Vol. 30, pages 3338 to 3346

Document 2: zum Buschenfelde C.M. et al., The generation of both T killer and Th cell clones specific for the tumor-associated antigen HER2 using retrovirally transduced dendritis cells, J. Immunol., 2001, Vol. 167, pages 1712 to 1719

Document 3: Moscatello D.K. et al., A naturally occurring mutant human epidermal growth factor receptoe as a target for peptide vaccine immunotherapy of tumors, Cancer Res., 1997, Vol. 57, pages 1419 to 1424

Document 4: Sato Y. et al., Immunological evaluation of peptide vaccination for patients with gastric cancer based on pre-existing cellular response to peptide, Cancer Sci., 2003, Vol, 94, pages 802-808

Document 5: Mine T. et al., Immunological evaluation of CTL precursor-originated vaccines for advance lung cancer patients, Cancer Sci., 2003 Vol, 94, pages 548 to 556

Document 6: Ullrich A. et al., Human epidermal growth factor receptor cDNA sequence and aberrant expression of the amplified gene in A431 epidermoid carcinoma cells, Nature, 1984, Vol. 309, pages 418 to 425

Document 7: Baron A.T. et al., Monoclonal antibodies specific for peptide epitopes of the epidermal growth factor receptor's extracellular domain, Hybridoma, 1997, Vol. 16, pages 259 to 271

Document 8: JP, 2002-525382, A (The Children medical center Corporation), 13 August, 2002 (13.08.02), full text (particularly, sequence number 63)

The subject matter of claim 10 does not appear to be novel or to involve an inventive step in view of the invention of document 7 cited in the ISR.

The antibody of the aforementioned claim cannot be distinguished from the antibody of document 7.

The subject matters of claims 1 and 3 do not appear to be novel or to involve an inventive step in view of the invention of document 8 cited in the ISR.

The peptide of the aforementioned claim cannot be distinguished from the antibody of document 7.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000786

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject matters of claims 1 and 3-10 do not appear to involve an inventive step in view of the inventions of documents 1-6 cited in the ISR.

Documents 1-5 are found to describe that various kinds of tumor originated polypeptides that can derive specific cytotoxic T cells for inhibiting proliferation of tumor cells and various kinds of tumor-originated polypeptides deriving specific cytotoxic T cells and having a specific antibody producing capability have been acquired. Document 6 describes amino acid sequences of EGFR and base sequences coding the amino acid sequences and a growth of EGFR in tumor cells.

Accordingly, a person skilled in the art could have easily conceived deriving specific cytotoxic T cells from a class of polypeptides consisting of amino acid sequences of a part of amino acid sequences described in document 6 and selecting and acquiring polypeptide having a specific antibody producing capability referring to the descriptions of cited documents 1-5 for impairing tumor cells.

At this time, a person skilled in the art could have easily produced pharmaceutical compositions containing obtained polypeptides and nucleic acids coding the polypeptides, derived and acquired EGFR reactive cytotoxic T cells using the polypeptides and acquired antibodies against the polypeptides.

Achievement of the subject matters of the aforementioned claims is not found to exhibit a noticeable effect.

The subject matters of claims 4 and 5 do not appear to involve an inventive step in view of document 8 cited in the ISR.

A person skilled in the art could have easily conceived acquiring nucleic acids coding the peptides described in document 8 and acquiring vectors containing the nucleic acids.

The subject matters of claims 4 and 5 do not appear to involve an inventive step in view of document 8 cited in the ISR.

The subject matter of claim 2 is neither described in any of the documents cited in the ISR nor obvious to a person skilled in the art.